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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/763,393

01/26/2004

Richard L. Veech

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EXAMINER

THOMAS, TIMOTHY P

ART UNIT

PAPER NUMBER

1628

MAIL DATE

DELIVERY MODE

03/16/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/763,393	Applicant(s) VEECH, RICHARD L.	
	Examiner TIMOTHY P. THOMAS	Art Unit 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32 and 34 is/are rejected.
- 7) ☒ Claim(s) 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/23/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicants' arguments, filed 12/23/2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

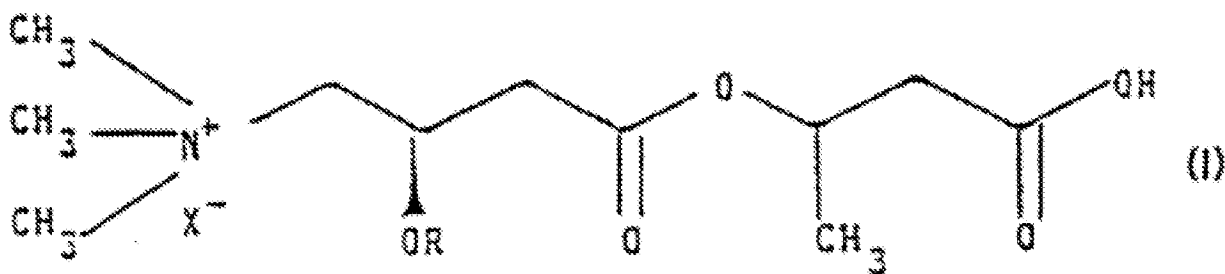
2. Applicant's arguments, see pp. 3-5, filed 12/23/2009, with respect to the rejection of claims 32-34 under 35 USC 103 have been fully considered and are persuasive. The rejection of claims 32-34 has been withdrawn.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tinti et al. (EP 0 443 996 A1; 1991).

Tinti teaches esters of beta-hydroxybutyric acid and pharmaceutical compositions containing them for inhibiting neuronal degeneration (title, abstract); compounds of formula (I) have the structure (abstract; para. 0001):



; these compounds are active in inhibiting neuronal degeneration as it occurs in Alzheimer's senile dementia (paragraph 0002); doses of the compounds in ranges from 5 or 15 to 500 mg in phials or tablets are administered (paragraph 0067); preferred dosages of 10-50 mg/kg , larger doses can be safely administered in view of the low toxicity of the compounds of the invention (10-50 mg/kg corresponds to 700-3500 mg administered to a 70-kg adult; paragraph 0066).

The compounds of formula (I) taught by Tinti, which are esters of beta-hydroxybutyric acid (a mixture of both D and L isomers) would be metabolic precursors of D-β-hydroxybutyric acid and acetoacetate; the ester moiety would be expected to be hydrolysed *in vivo* resulting in the required elevation of the patient's ketone bodies. Esters of D-β-hydroxybutyric acid are specifically indicated to be useful in the instant invention (see instant specification, p. 20, lines 7-31). Therefore, the beta-hydroxybutyric acid esters taught by Tinti, absent evidence to the contrary, are taken to satisfy the required metabolic precursor, and hydrolysis of the ester bond would result in the required elevation of blood levels of D-β-hydroxybutyric acid and acetoacetate. Although Tinti is silent about levels of D-β-hydroxybutyric acid and acetoacetate achieved by the compounds taught, at the highest doses, it would be expected that (at some time point) the blood level would achieve an elevated concentration within the

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required elevated concentration range of 0.3mM to 20 mM, meeting the requirements of the instant claims.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Since dementia involves loss of cognitive abilities, including in the area of memory, treating Alzheimer's senile dementia is considered to read on treating memory loss, recited in claim 32 and treating memory loss in Alzheimer's disease, required by claim 34.

It would have been obvious to administer the compounds of Tinti at the highest doses taught to an individual with memory loss in Alzheimer's disease, meeting the required step of the instant method claims. The motivation would have been the suggestion of Tinti that these compounds are suitable for treating Alzheimer's senile dementia.

Claim Objections

5. Claim 33 is objected to because it depends on a rejected base claim.

Appropriate correction is required.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Examiner, Art Unit 1628